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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: NIKOLAI I. AFANASENKO ET AL. (PCT)
SERIAL NO.: 08/646,213 GROUP: 3302
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FOR: DEVICE FOR TREATMENT OF PATIENTS WITH DISTURBED
POSTURE AND MOTOR ACTIVITY

DECLARATION UNDER RULE 132

ATTN: BOX FEE AMENDMENT
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, EVGENY GRIGORIEVICH SOLOGUBOV, Cand. Sc. (Med.), declare
that I am Head Physician of the Regional Psychoneurological
Hospital No. 18 GMU, Moscow, since 1983; and

that the following clinical tests (EXHIBIT B) were conducted
under my supervision:

EXHIBIT B

MEDICAL COMMENT

on clinical trials of the device
(therapeutic suit π K-92 "Adeli")
for treating patients with disturbed locomotorium.

Clinical trials of the therapeutic suit π K-92 "Adeli" for
treating patients with disturbed locomotorium were carried out from
March 15, to April 28, 1993, on the basis of the Children's
Clinical Psychoneurological Hospital No. 18 in Moscow.

A total of 19 patients ages from 15 to 17 were treated, their clinical diagnoses and generalized neurologic-orthopedic examination findings being as follows:

1. Bal., 17. Diagnosis: ICP, spastic diplegia.
2. Kar., 17. Diagnosis: ICP, spastic diplegia, predominantly right-side, right equinus contracture, postoperative status.
3. Kom., 17. Diagnosis: ICP, spastic diplegia, predominantly right-side, talipes equinus, instability of the hip joints, markedly pronounced lumbar lordosis.
4. Kon., 16. Diagnosis: ICP, hemiparetic form.
5. Mal., 16. Diagnosis: ICP, spastic diplegia.
6. Pol., 17. Diagnosis: ICP, hyperkinetic form.
7. Tish., 16. Diagnosis: ICP, spastic diplegia, rotational-adduction and flexural contracture of the hip joints, subluxation of the 1st metatarsal bone in the right foot, I degree scoliosis.
8. Yak., 16. Diagnosis: ICP, spastic diplegia, predominantly right-side, with a considerable shortening of the left leg and obliquity of the pelvis.
9. B.Yu., 16. Diagnosis: ICP, spastic diplegia, predominantly right-side, atactic syndrome, and spastic dysarthria.
10. S.E., 20. Diagnosis: ICP, spastic diplegia, predominantly right-side.
11. V.S., 14. Diagnosis: ICP, spastic diplegia, predominantly right-side, mild internal rotation of the hip joints.

12. U.N., 22. Diagnosis: ICP, hyperkinetic form, hyperkinetic dysarthria.

13. B.I., 18. Diagnosis: ICP, spastic diplegia, predominantly right-side, hyperkinetic syndrome, spastic-hyperkinetic dysarthria.

14. R.N., 17. Diagnosis: ICP, spastic diplegia, predominantly right-side, hyperkinetic syndrome.

15. Sh.L., 12.5. Diagnosis: spastic diplegia, severe degree hyperkinetic form, psycho-organic syndrome.

16. T.I., 16. Diagnosis: ICP, spastic diplegia, predominantly right-side, hyperkinetic syndrome, right talipes equinus, status after Barr's operation.

17. K.Yu., 13. Diagnosis: ICP, spastic diplegia, hyperkinetic syndrome, status after Barr's operation and bringing down the straight femoral muscles, psycho-organic syndrome.

18. M.Yu., 15. Diagnosis: ICP, spastic diplegia, predominantly right-side, hyperkinetic syndrome, right talipes equinus, internal potential syndrome, psycho-organic syndrome involving intellectual degradation.

19. Sh.A., 16. Diagnosis: ICP, spastic diplegia, status after bilateral Sayre's and Eggers operations.

The signs of intracranial hypertension, as well as dilatation of the cerebral ventricles were detected in all the patients, using the echoencephalography technique.

The electroencephalograms obtained from a majority of patients displayed an unstable polymorphous rhythm and only fragments of the

alpha-rhythm. The epileptic signs of the peak-wave type were displayed in the electroencephalograms of two patients.

According to the rheoencephalography findings, there were detected in the child patients asymmetrical dystonic phenomena, predominantly in the zone of vertebral circulation, as well as the signs of phlebostasis.

The pulse rate and blood pressure values were in the age-dependent limits.

Psychological and pedagogical examination of the child patients established a low intellectual level of the children, as well as the following characteristic features: difficulties in attracting attention, disorders of psychical activity (involving abrupt swings from passive behavior to the state of disinhibition and rampancy), obstinacy, impulsiveness, sometimes spitefulness and reduced social interests.

A thorough clinicoparaclinical examination of the patients was followed by functional tests, using a loading suit of the "Adeli" type, that is, the patients wore the suit for 30-60 min. within a three-day period while walking in an ordinary manner without special loads. Once the vegetative phenomena in the patients had normalized and the children had adapted to the loading suit, the effective period of treatment began, which lasted 10-11 days with

the maximum duration of a treatment session of one hour and a half. No sessions were carried out in the days of rest and holidays.

It is worth noting that all the children visited the polyclinic in the second half of the day after school hours (9 and 10 forms) and a bus-journey across the entire city, and then returned to their boarding school and did their lessons. All of them complained of not having their sleep out. The preplanned treatment course was not completed due to the quarantine in the boarding school on account of an intestinal infection. Thus, throughout the observation period each of the patients was given a total of only 16 treatment sessions, being moreover in a state of increased fatiguability and reduced working capacity.

Despite a shortened cycle by the method being trialled and the aforementioned adverse circumstances of its conduction, all the patients treated exhibited a positive result.

1. All the patients displayed an enhanced vigor, that is, better state of being and spirits, increased attentiveness, self-reliance, and social activity; by the way, the attendance of the treatment sessions was good, and there were no late-comers.

2. In all the patients the vertical position in the standing posture was improved (that is, it became more stable, and the forward inclination of the body decreased), frontal body rocking while walking was reduced, and the pace got wider.

3. Variation in the myogenic tonus decreased, and active moments of the arms and legs were facilitated, that is, the amount of spreading the thighs apart in the supine position increased by 2 cm (Kar.), by 6 cm (Bal., Kom.), by 8 cm (Mal.), and even by 12 cm (Pol. and Tish.).

4. The tendon reflexes normalized.

5. The degree of triple flexion of the legs reduced in four patients.

6. The foot roll-over from the heel to the toe appeared in four patients.

7. The degree of lumbar lordosis in some of the patients decreased from 1.5 cm to 7 cm.

8. Talipes equinovarus decreased in two patients.

9. Patient Pol. exhibited a considerably reduced choreoathetoid hyperkinesis.

10. The level of energy consumption for walking decreased.

The aforelisted neurologic-orthopedic findings were corroborated by the positive shifts in electroencephalograms taken from the patients treated, wherein the following particulars were

noted: reduced signs of dysfunction of the mesodiencephalic structures and reduced irritation phenomena of the trunkal formations, disappeared elliptoid complex, and an increased stability of the main cortical rhythms with the rhythmicity as a whole approximating the age-related norm. No negative changes in the EEG of any patients were revealed. Positive shifts in the psychic status and the locomotor functions of the patients were confirmed by their parents and teachers.

Conclusion: Treatment of the locomotor disturbances in patients with ICP with the aid of the therapeutic suit π K-92 "Adeli" yields a distinct positive result when applied not only under hospital but also under ambulant clinical conditions, to patients with a prolonged age of the disease and the presence of the resultant severe pathologic synergies and deformities in the locomotorium.

Thus, both the suit π K-92 "Adeli" and the method of functional-fixing correction and adaptive biological control can be recommended for use in medical practice for treating patients with ICP and other locomotorium disturbances, and the suit π K-92 "Adeli" can be recommended for a quantity production.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the

like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 10. 02. 982.



Name: Evgeny Grigorievich Sologubov
Title: Head Physician

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